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1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF NEW YORK

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3 TEVA PHARMACEUTICALS USA,  
4 INC., et al.,

Plaintiffs,

5 v.

08 CV 7611 (BSJ)

6 SANDOZ, INC., et al.,

7 Defendants.

8 -----x

9 New York, N.Y.  
10 November 3, 2011  
4:05 p.m.

11 Before:

12 HON. BARBARA S. JONES,

13 District Judge  
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1 (In chambers; all counsel appearing via speakerphone)

2 THE COURT: Good afternoon. We have a court reporter  
3 so let me just go around and ask each of you to let me know who  
4 will be speaking, and then I will ask you to identify  
5 yourselves again when you speak.

6 Who will be speaking for Teva?

7 MS. HOLLAND: It's Elizabeth Holland of Kenyon &  
8 Kenyon, your Honor.

9 THE COURT: I remember you, Ms. Holland.

10 How about Sandoz?

11 MR. DOYLE: This is David Doyle, your Honor, and I  
12 will speaking for Sandoz.

13 THE COURT: Thank you, Mr. Doyle.

14 And Mylan?

15 MS. BLOODWORTH: Good afternoon, your Honor. This is  
16 Shannon Bloodworth from Perkins Coie.

17 THE COURT: Thank you.

18 Well, it appears that your client has amended,  
19 Mr. Doyle, has amended their ANDA.

20 What is Teva's position, what do you want to do?

21 MS. HOLLAND: Your Honor, we think there are some  
22 procedural issues with Sandoz trying to enlarge the record  
23 after trial. We also think the timing of the amendment was  
24 strange. It was filed October 28 which, of course, is after we  
25 submitted our opposition brief but before we submitted our

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1 reply, but we didn't actually receive the amendment until it  
2 was attached to Sandoz's reply. But --

3 THE COURT: Yeah, I know.

4 MS. HOLLAND: -- setting all that aside, I think as a  
5 practical matter the most prudent thing for the Court to do at  
6 this point in time would be to make findings and conclusions  
7 based on both the old ANDA process and the viscometer process  
8 because frankly, your Honor, this has been a moving target. We  
9 don't know if the FDA is going to accept the viscometer method  
10 as a substitute for the time and temperature method.

11 In terms of the evidence, we already established  
12 through Dr. Gokel's testimony at trial that the viscometer  
13 method, which is the method in the amendment, does infringe  
14 literally or alternatively under the doctrine of equivalent.  
15 So we believe the record as it stands establishes infringement  
16 for the method that is in the new ANDA amendment.

17 THE COURT: Two things. So you believe I -- and  
18 you're content with the record I have now if I decide to also  
19 make a determination of infringement with this new viscometer  
20 amendment. Is that right?

21 MS. HOLLAND: Yes, your Honor.

22 THE COURT: Okay. And I guess the only thing I don't  
23 understand is is it possible -- and maybe Mr. Doyle can chime  
24 in as well -- is it possible this amendment will not be  
25 accepted? I understand the FDA passes on the ANDA product.

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1 But can they actually say, well, sorry, we're not accepting  
2 this amendment?

3 I mean I really do not want to start opining on  
4 something that's not ever going to be a product. I'm a little  
5 confused maybe just procedurally with the FDA.

6 MR. DOYLE: Your Honor, my understanding is that just  
7 accepting that, of course, anything could happen before any  
8 regulatory agency, that is, it is exceptionally unlikely that  
9 the FDA would not accept this.

10 And I can also tell the Court that as Dr. Bishop  
11 testified at trial, it has been Sandoz' intent for a  
12 considerable period of time for this to be the method and it is  
13 the method that they're currently using and it is the method  
14 that they intend to use to produce their final product once  
15 they obtain the regulatory approval.

16 THE COURT: Well, you're obviously content with the  
17 idea that I should consider it and make findings.

18 And I gather you are as well, is that right, speaking  
19 for Teva?

20 MS. HOLLAND: Yes, your Honor. My point earlier was  
21 that Sandoz can file whatever it wants with the FDA, but the  
22 FDA may come back later down the road and say, you know what,  
23 we don't like the viscometer method, go back to the time and  
24 temperature, which is why I said it would probably be prudent  
25 to consider both in terms of the findings and conclusions from

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1 trial.

2 THE COURT: Okay. But basically it's amended, for all  
3 practical purposes, and everybody agrees that I should consider  
4 both, correct, both methods?

5 MR. DOYLE: Yes, your Honor, for Sandoz and Momenta.

6 MS. HOLLAND: Yes, your Honor.

7 THE COURT: Now, there are batches in the amendment.  
8 Are they new? Is there anything that anyone needs discovery on  
9 with respect to that?

10 MR. DOYLE: I don't think so, your Honor.

11 THE COURT: Mr. Doyle, no, it wouldn't be you. I  
12 guess I'm really talking to --

13 MS. HOLLAND: No, your Honor, we don't think there's  
14 further discovery required.

15 THE COURT: Good.

16 MS. HOLLAND: -- wasn't going to do anything else --  
17 enrich the record with additional submissions.

18 As you know, your Honor, what was attached to  
19 Ms. Hagberg's declaration was not the full amendment, so we're  
20 assuming that that's the only part that's going to be  
21 submitted.

22 THE COURT: Is that correct, Mr. Doyle?

23 MR. DOYLE: It is, your Honor.

24 THE COURT: Okay. Then we're fine. I'll rule on  
25 both.

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1 MS. HOLLAND: Just to be clear, your Honor, part of  
2 the amendment that I don't believe was attached actually had  
3 the backup time and temperature model that Dr. Gokel had  
4 discussed at trial. It actually was submitted. I believe what  
5 was attached in the Hagberg declaration was the new batch  
6 record, but the old one was submitted as well.

7 THE COURT: Okay. Fair enough.

8 The other issue is the stay that I imposed with  
9 respect to the GAD patent case.

10 I'll hear from you, Mr. Doyle and Ms. Bloodworth.

11 MR. DOYLE: Your Honor, we do request that the Court  
12 continue that stay until it does have an opportunity to address  
13 the pending motions to dismiss. They do raise what we believe  
14 is a dispositive legal issue. And as I know your Honor  
15 appreciates, the discovery in this type of case is extensive  
16 and very expensive and we would request that the Court continue  
17 the stay to -- finally have a chance -- I know you've been  
18 working very hard on our case and we're not complaining in any  
19 way whatsoever. But we do think that that's -- we should not  
20 go forward with the expense of discovery and the disruption of  
21 business that it causes until your Honor has had a chance to  
22 get to those motions.

23 THE COURT: Okay. Ms. Bloodworth, are you of the same  
24 mind?

25 MS. BLOODWORTH: Yes, your Honor, with the added issue

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1 that Natco is an individual party in this case and they are of  
2 course located in India and there has been no evidence that  
3 Natco has made any use of these markers outside of India and of  
4 course is no longer using these markers.

5 We did amend our ANDA in April. The testimony in  
6 September by Dr. Owens was very clear that we are no longer  
7 using these markers. So, for our purposes, because the markers  
8 are used in India to produce the product, we believe that the  
9 change in the use from the peptide markers to the universal  
10 calibration system is dispositive of our motions and that there  
11 is no colorable cause of action any longer.

12 THE COURT: All right.

13 Ms. Holland.

14 MS. HOLLAND: Just to be clear, your Honor, there was  
15 discovery in the Mylan case. The stay was an agreed upon stay  
16 in the Mylan case --

17 THE COURT: Right, I remember, yeah.

18 MS. HOLLAND: -- so the case was proceeding on its  
19 course. We believe it should continue to proceed. The  
20 schedule that we presented to your Honor we believe is one that  
21 could accommodate ruling on the motion but at the same time  
22 having the case go forward as it has been going forward.

23 I want to address Ms. Bloodworth's point about  
24 changing the markers. Again, it's not at all clear that the  
25 FDA would even accept whatever Sandoz or Mylan has submitted on

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1 that issue. As it stands, they developed their product using  
2 what the testimony at trial showed they knew were infringing  
3 markers. That was clear from the testimony at trial.

4 That action should go forward, stay its course as the  
5 Mylan case had been going forward. And we put in a schedule  
6 that could put both cases on the same track, not unduly quickly  
7 but in enough time that everything can get done and there can  
8 be a ruling on the motion.

9 THE COURT: Let me just take a look at your schedule.  
10 Give me a second.

11 Well, I'll tell you what. I'm not prepared to make a  
12 decision based on any type of review of your motion because I  
13 haven't looked at them, and I would feel a lot better making  
14 the decision about what to do with going forward with discovery  
15 once I had a chance to review them.

16 So I'm going to continue the stay, which I guess was  
17 technically over two days ago or three days ago, until mid  
18 December. We'll make it December 15. And we'll have another  
19 conference then. And I promise you that I will have a better  
20 sense of what I want to do because I will have at least been  
21 able to review the papers and I'll have had more time to review  
22 them. Okay.

23 MR. DOYLE: Yes, your Honor. Thank you.

24 MS. HOLLAND: Thank you, your Honor.

25 THE COURT: All right. Is there anything else we need



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1 to deal with then? I mainly just wanted to make sure that I  
2 didn't -- no one needed to send me any additional briefing, or  
3 anything else for that matter.

4 MR. DOYLE: Nothing from Sandoz or Momenta, your  
5 Honor.

6 THE COURT: Okay.

7 MS. BLOODWORTH: Nothing further, your Honor. Thank  
8 you.

9 THE COURT: And, Ms. Holland, we're all set?

10 MS. HOLLAND: We're all set, your Honor. Thank you.

11 THE COURT: Okay. Thank you.

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